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Trend towards primary closure following laparoscopic exploration of the common bile duct

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ABSTRACT

INTRODUCTION The aim of this study was the assessment of patient outcome, peri-operative complications, length of stay and duration of operation after laparoscopic primary closure of the common bile duct (CBD) compared with choledochotomy with T-tube drainage and trans-cystic exploration.

PATIENTS AND METHODS Analysis of prospectively collected data on 71 explorations of the common bile duct between July 2001 and March 2006.

RESULTS A total of 71 patients had exploration of the CBD. Within this group, 12 were referred after failed endoscopic retrograde cholangiopancreatography (ERCP). The methods of exploration included trans-cystic (9 cases), choledochotomy with T-tube (12), and choledochotomy with primary closure (50). CBD stones were found in 66 patients. In the remaining cases, we found a stricture in 1, debris in 2, and dilatation of the CBD without a stone in 2. There were 5 conversions to open technique and 3 patients required postoperative ERCP (1 with permanent stenting). Peri-operative complications included T-tube (3), primary closure group (9), and trans-cystic (0). There was no statistical significant difference (Chi-square test, $P = 0.296$) between the groups. There was a trend towards a shorter length of stay in the primary closure group as compared with the trans-cystic and T-tube groups of 4.16, 4.44, and 6.33 days, respectively. However, it did not reach statistical significance (one-way analysis of variance with Boneferroni correction, mean difference between groups 1.89, 0.28, 2,17, statistical significance at $P < 0.05$). The shortest operating time was in the primary closure group (95.92 min) which was statistically significant ($P < 0.001$). We did not use a biliary drain in the last 48 patients.

CONCLUSIONS Primary laparoscopic closure of the CBD is safe and results in a reduction in operating time. Choledochoscopy ensures clearance of the CBD and eliminates the need for T-tube.

KEYWORDS

Common bile duct – Primary closure – T-tube drainage – Trans-cystic exploration

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The aim of this study was to assess patient outcome after primary closure of the CBD compared with closure with a T-tube drain (T-tube) and trans-cystic exploration. Assessment included length of stay, duration of operation, incidence of complications and their type.

Patients and Methods

This study was a prospective analysis carried out between July 2001 and March 2006. In this period, we included all cases resulting in exploration of the common bile duct whether laparoscopically (LECBD) or by open technique after conversion (LOECBD). All procedures were performed by one consultant surgeon (ALB). We recorded standard patients' demographics including age, gender, American Society of Anesthesiologists (ASA) grade, as well as the indication for surgery. We analysed the results of liver function tests (LFTs), ultrasonography of the biliary tree and magnetic resonance cholangiopancreatography (MRCP) if performed. Collected data included the duration of operation, findings on intra-operative cholangiogram (IOC) and choledochoscopy, route of exploration of the CBD as well as the method of closure and causes for conversion to open technique. Complications were recorded during the patients' hospital stay, at 6-week follow-up or later if referred back to the clinic or re-admitted. Finally, we compared the patients' postoperative stay.

Operative technique

Laparoscopic cholecystectomy was performed using a standard 4-port technique. We used a 30° video-laparoscope (Stryker, USA) placed through a 10-mm umbilical port

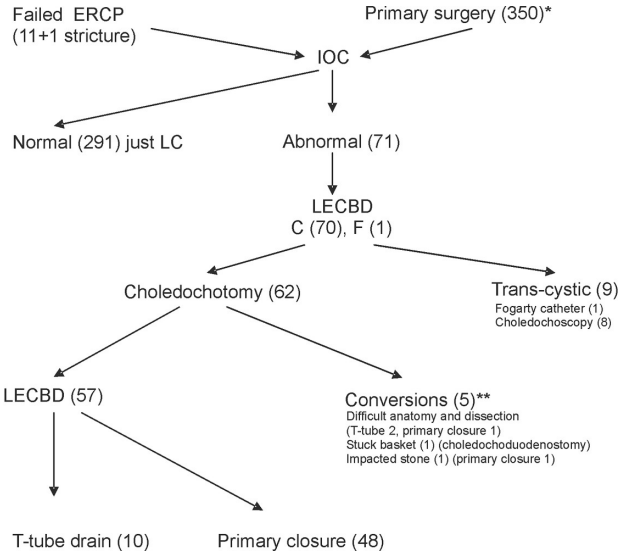

Figure 1 Management of choledocholithiasis. C, choledochoscopy; ERCP, endoscopic retrograde cholangiopancreatography; F, Fogarty catheter; IOC, intra-operative cholangiogram; LC, laparoscopic cholecystectomy; LECBD, laparoscopic exploration of the common bile duct. *Patients with pre-operative diagnosis of cholecystocholithiasis and/or choledocholithiasis considered for primary LC + IOC ± LECBD. **Retrieval with Dormia basket (4), open choledochoduodenostomy for stuck Dormia basket (1).

inserted by the open Scandinavian method in all patients. A 10-mm port was placed in the subxiphisternum and two 5-mm ports in the right abdomen. In the case of gross distension of the gallbladder, its contents were aspirated with a Veress needle. During LECBD, one 5-mm port was converted to a 12-mm one to accommodate the operating choledochoscope (Olympus, Tokyo, Japan). The operation was started with dissection of Calot's triangle and double clipping and division of the cystic artery. Routine trans-cystic IOC was performed via an additional stab incision in the right hypochondrium. The gallbladder was left *in situ* and used for retraction until LECBD was completed. In cases of a trans-cystic approach to the CBD, where direct exploration of the CBD was considered inappropriate or where the cystic duct was dilated sufficiently to allow CBD exploration through it, the choledochoscope was passed through a partially divided cystic duct. Once stones were retrieved, the cystic duct was double clipped or ligated with a Surgitie (Autosuture, Tyco, USA). When the CBD was approached directly, a longitudinal supraduodenal choledochotomy was made using a Berci knife and microscissors. In cases where the anatomy of the extrahepatic bile ducts was not obvious, we used needle aspiration of bile to identify the CBD. Common bile duct stones were retrieved using a wire basket in all but one patient in whom a single stone was removed with the aid of a Fogarty catheter. After all stones were retrieved and clearance of the CBD confirmed with choledochoscopy, the choledochotomy was closed with interrupted 3.0 vicryl sutures on a ski needle (Johnson & Johnson). A non-suction drain was placed in the gallbladder bed in all patients. It was removed the next day or, in cases of bile leak, when drainage ceased. In patients in whom we used a T-tube drain, it was placed in the choledochotomy and secured with the same sutures. The T-tube was ligated after 24 h. In the absence of pain and when the patient's general condition permitted, they were discharged with the T-tube *in-situ* and re-admitted for an overnight stay 3–4 weeks later to have it removed. We did not perform a routine tubogram prior to T-tube removal, having already performed an on-table completion tubogram at operation.

Follow-up

All patients were routinely assessed 6 weeks after discharge or if re-referred for complications after this period. One patient died on the third postoperative day; all other patients attended their follow-up.

Table 1 Baseline clinical variables of patients having exploration of the common bile duct

	Primary closure	T-tube	Trans-cystic
Age median, range (years)	70.5 (19–90)	71.5 (29–84)	62 (29–87)
M/F ratio	13:37	3:9	2:9
ASA			
I	7	0	3
II	29	10	4
III	13	1	2
IV	1	1	0
Elective	22	4	3
Same admission	28	6	5
Interval	0	2	1
Indication for surgery			
Obstructive jaundice	9	4	2
Biliary colic	10	1	0
Acute cholecystitis	11	3	2
Chronic cholecystitis	5	1	2
Acute pancreatitis	4	1	2
Cholangitis	3	2	1
Obstructive jaundice & acute cholecystitis	5	0	0
Acute on chronic pancreatitis	3	0	0

Statistical analysis

SPSS for Windows v.12.0 statistical analysis software was used to carry out Chi-square analyses on nominal categorical data (complication rate) and one-way analysis of variance (ANOVA), with Boneferroni correction for multiple comparisons, on continuous data (duration of operation and length of stay). Variables were considered statistically significant with $P < 0.05$.

Results

Between July 2001 and March 2006 (57 months), we performed 71 laparoscopic explorations of the CBD (Fig. 1). Baseline clinical variables of the patients are shown in Table 1. Twelve patients were referred for surgical management of CBD stones and completion LC after failed ERCP (Table 2 and Fig. 1). IOC was obtained in all patients. Access to the CBD was either trans-cystic (9; 12.67%), or directly through the CBD (62; 87.33%). There were 5 (7%) conversions to open: difficult anatomy and dissection (3), impacted stone in the CBD (1) and impacted Dormia basket (1). After direct exploration of the CBD, we used a T-tube drain in 12 cases, and closed it primarily in 50. Choledochoscopy was performed in almost all cases (one Fogarty catheter in trans-cystic group). On exploration of the CBD, we found stones in 66 (92.95%) patients, a benign stricture in one, dilatation without stones in 3 (false positive IOCs), and dilatation with debris in 2. In the trans-cystic method, clearance was achieved in 6 (66.6%) and in direct CBD exploration in 57 (91.9%) patients. Overall, clearance of the CBD was accomplished laparoscopically in 63 (88.73%) cases. Three patients in the trans-cystic group required postoperative endoscopic retrieval of retained stones (Table 3). One patient required permanent stenting of the CBD after 3 failed ERCPs. In one patient, with an impacted Dormia basket, we performed open choledocho-duodenostomy. Our use of the T-tube became less frequent and we did not use it in the last 48 cases. Unexpected CBD stones (normal or non-visualised CBD on ultrasound scan, normal LFTs, and with no clinical suspicion on history or clinical examination) were found in 17 (23.94% of LECBD and 4.5% of LC) patients (Table 4). The shortest operating time was in the primary closure group (mean, 95.92 min; range, 55–130 min) as compared with the trans-cystic (mean 119.22 min; range, 73–140 min) and T-tube groups (138.58 min; range, 107–168 min). The mean difference between the primary closure and trans-cystic groups was –23.3 (95% CI –37.5 to –9.2; $P < 0.001$). The mean difference between the primary closure and T-tube groups was –42.7 (95% CI –55.2 to –30.1; $P < 0.001$). The difference between the trans-cystic and T-tube groups was not statistically significant (–19.4; 95% CI –36.6 to –2.1; $P = 0.022$; Tables 5 and 6.) The length of postoperative stay was the shortest in the primary closure group (mean, 4.16 days; range, 1–20 days) compared with the trans-cystic (mean, 4.44 days; range, 1–13 days) and T-tube (mean, 6.33 days; range, 2–13 days) groups. The mean difference between the primary closure and trans-cystic groups was –0.28 (95% CI –3.50 to 2.93; $P = 1$). The mean difference between the primary closure and T-tube groups was –42.7 (95% CI –5.02 to 0.68; $P = 0.197$). The difference between the trans-cystic and T-tube groups was –2.17 (95% CI –5.80 to 2.02; $P = 0.720$; Tables 5 and 6). Despite the primary closure group having a trend towards a shorter hospital stay than the other groups, it did not reach statistical significance.

Table 2 Patients referred for exploration of the CBD following ERCP

Failure to cannulate the CBD	7
Sphincterotomy only, second presentation with impacted stones	3
Sphincterotomy, failure to retrieve stones	2

Table 3 Laparoscopic failures of CBD clearance

Conversions	
Difficult anatomy and dissection	3
Impacted CBD stone	1
Impacted Dormia basket	1
Inaccessible CBD stones, postoperative ERCP	
Anatomical variations in cystic duct insertion onto the CBD*	3

*All in trans-cystic approach.

Table 4 Ultrasound and liver function test findings in patients with confirmed choledocholithiasis

Ultrasonography findings	Abnormal LFTs	Normal LFTs
Not done	1 (1.4%)	0
CBD dilated no stone	8 (11.3%)	10 (14.8%)
CBD dilated & stone	17 (23.9%)	7 (8.8%)
Normal or not visualised CBD	11 (15.5%)	17 (23.9%)

Table 5 Length of stay and operating time, one-way analysis of variance (ANOVA)

	Sum of squares	df	Mean square	F	*P*-value
Operating time					
Between groups	19393.341	2	9696.670	38.295	0.000
Within groups	17218.152	68	253.208		
Total	36611.493	70			
Hospital stay					
Between groups	45.856	2	22.928	1.757	0.180
Within groups	887.609	68	13.053		
Total	933.465	70			

Mortality and morbidity

Overall, there were 12 complications (16.9% total complication rate) and 1 (1.29%) postoperative death (Tables 7 and 8). In the group treated with T-tube biliary drainage, there were 3 (25%) non-fatal complications: incisional hernia following conversion to open technique (1), pyrexia of unknown origin (1) and supraventricular tachycardia (SVT; 1) that required treatment in HDU on the first postoperative day. In patients with primary closure, there was 1 (2%) death in a 90-year-old woman, ASA 3, with gallstone pancreatitis who died from bowel ischaemia. There were 8 (16%) non-fatal complications including three bile leaks, two from the choledochotomy site requiring early re-operation and one from the gallbladder bed treated conservatively with suction drainage. Other complications included: urinary retention (1), self-limiting SVT (1), hyperkalaemia (1), and sepsis required prolonged stay on ITU (1). This patient was admitted as an emergency with severe cholecystitis which perforated pre-operatively. The complication rate between the three groups did not reach statistical significance (Chi-square, $p = 0.296$) In the trans-cystic group, there were no recorded complications;

Table 6 Operating time and length of stay: Boneferroni correction for multiple comparisons on continuous data

Dependent variable	(I) group	(J) group	Mean Difference (I–J)	SE	*P*-value	95% CI
Operating time						
	Primary	Trans-cystic	–23.30*	5.762	0.000	–37.45 to –9.16
		T-tube	–42.66*	5.115	0.000	–55.22 to –30.11
	Trans-cystic	Primary	23.30*	5.762	0.000	9.16 to 37.45
		T-tube	–19.36*	7.017	0.022	–36.58 to –2.14
	T-tube	Primary	42.66*	5.115	0.000	30.11 to 55.22
		Trans-cystic	19.36*	7.017	0.022	2.14 to 36.58
Hospital stay						
	Primary	Trans-cystic	–0.28	1.308	1.000	–3.50 to 2.93
		T-tube	–2.17	1.161	0.197	–5.02 to 0.68
	Trans-cystic	Primary	0.28	1.308	1.000	–2.93 to 3.50
		T-tube	–1.89	1.593	0.720	–5.80 to 2.02
	T-tube	Primary	2.17	1.161	0.197	–0.68 to 5.02
		Trans-cystic	1.89	1.593	0.720	–2.02 to 5.80

*The mean difference is significant at the 0.05 level.

Table 7 Total rate of complications: cross-tabulation

		Group			Total
		Primary	Trans-cystic	T-tube	
None	Count	41	9	9	59
	Expected count	41.5	7.5	10.0	59.0
Complications	Count	9	0	3	12
	Expected count	8.5	1.5	2.0	12.0
Total	Count	50	9	12	71
	Expected count	50.0	9.0	12.0	71.0

however, we were not able remove stones in 3 (33.3%) patients because of anatomical constraints.

Retained stones

In this series, we encountered CBD stones that we were not able to retrieve laparoscopically. It is important to emphasise that there were no cases of unintentionally missed stones. All were identified on IOC and dealt with appropriately. In one case (T-tube group), a stone was retrieved after conversion to open technique. Three other patients in the trans-cystic group required postoperative ERCP.

Discussion

Traditionally, exploration of the common bile duct both with open surgery and laparoscopically was accompanied by the placement of a T-tube drain. The rationale for the use of a T-tube following CBD exploration was based on three main factors: (i) the potential for extraction of retained stones with the aid of a steerable catheter; (ii) as a method of achieving a controlled biliary fistula; and (iii) easy access for radiological visualisation of the CBD. Use of a choledochoscope enables direct visualisation of the CBD and ensures its complete clearance as well as inspection of the distal CBD for other possible causes of obstruction at the level of the sphincter of Oddi. However, there are numerous reports of complications specifically associated with the use of a T-tube for biliary drainage. These occur after both open and laparoscopic exploration of the CBD. In general, complications include: fluid and electrolyte disturbances, sepsis, premature dislodgement, bile leak, localised pain, biliary peritonitis, prolonged biliary fistulae and late biliary stricture. It is important to note that the presence of a T-tube does not prevent bile leaks as they occur both when it is still *in situ*, as well as after its removal.[1–4]

Table 8 Chi-square tests: analysis of complications

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-square	2.434*	2	0.296
Likelihood ratio	3.878	2	0.144
Linear-by-linear association	0.030	1	0.862
Valid cases (*n*)	71		

*Two cells (33.3%) have expected count less the 5. The minimum expected is 1.52.

Previous studies comparing primary closure with T-tube drainage in open techniques[5] showed a significant reduction in hospital stay and duration of operation with comparable complication rates. Subsequently, Wu and Soper,[6] in a prospective randomised experimental animal study of different laparoscopic techniques of exploration and closure of the CBD, showed similar reduction in operating time. They also reported that primary closure of the CBD resulted in a significant increase in stenosis. However, earlier studies assessing safety and feasibility of primary closure after LECBD did not report such findings in humans with a median follow-up of 22 months.[7] Laparoscopic exploration of the CBD was a natural step forward once laparoscopic cholecystectomy became a standard technique for management of cholecystolithiasis. The rationale was the same as in the open technique – one-stage approach to common bile duct stones and avoidance of the ERCP and its associated cost and complications. Berci and Morgenstern, in 1994, in the multi-institutional SAGES study paved the way for laparoscopic extraction of common bile stones.[8] However, in their study, 83% of LECBDs were done via the trans-cystic route; in cases of choledochotomy, primary closure was never attempted and 95% of patients had a T-tube drain. In 1999,

Cuschieri *et al.*[9] in the EAES study concluded that the laparoscopic single-stage approach for management of gallstone disease and choledocholithiasis is a better option in fit patients, ASA 1 and 2. With different methods of CBD exploration, it was soon evident that a trans-cystic approach was not very satisfactory in achieving complete clearance of the CBD.[10] Over the years, other researchers compared LECBD with and without a T-tube drain. In the study of 38 patients, 12 with primary closure and 26 with Kehr's tube, Ha *et al.*[11] concluded that primary closure of the CBD was feasible and safe. With increasing acceptance of the technique and growing experience of surgeons, LECBD without biliary drainage became more widely practised. In our study, we achieved statistically significant shortening of operating time in the group of patients with primary closure as compared to trans-cystic LECBD or closure over the T-tube. There was also a trend towards reduced duration of hospital stay which did not reach statistical significance. A possible reason for the shorter hospital stay in patients with a T-tube may be explained by our local policy. Twenty-four hours postoperatively, the drain was clamped and patients were discharged home when their general state allowed. They were re-admitted 3 weeks later for T-tube removal, observed for 3–4 h and discharged if clinically well. None of the patients required overnight hospital stay. We agree with Decker *et al.*,[12] who emphasised that length of stay is not necessarily a major criterion for assessing the outcome of a surgical procedure. It is influenced by many other factors which are independent of a patient's postoperative recovery. Over the period of time, we used T-tube drainage less frequently as our approach changed from routine to very selective use. With growing experience, we considered the use of a T-tube appropriate only in cases of retained impacted stones that would require endoscopic extraction or cholangitis with frank pus in the CBD. Similarly, in 1967, Krauss and Kern,[13] in their report of 867 open choledochotomies with primary closure, advised T-tube drainage in cholangitis, gross inflammation or a very thin CBD. We have not used any form of biliary drainage during the last 48 cases. In this period, there were three cases of bile leak, one from the duct of Luschka treated conservatively with a suction drain, and two from the choledochotomy site. In the latter two cases, as the volume of bile in the drain was increasing and patients started to develop signs of localised biliary peritonitis, they underwent laparoscopy on the second postoperative day. On both occasions, the leak from the choledochotomy site was repaired with placement of a single additional suture. Both patients made a prompt and uneventful recovery. We, therefore, advocate early laparoscopy in such cases of suspected bile leak. Newer techniques of ante-grade biliary stenting have been described.[14–16] During LECBD, either trans-cystic or choledochotomy, a biliary stent is inserted to facilitate drainage. These stents require endoscopic removal. Such adjuncts to LECBD provide adequate biliary drainage without the complications associated with a T-tube and is possibly the next step forward in single-stage management of choledocholithiasis. In our series, 4 out of 5 conversions occurred in the first 19 out of a total 71 cases. Higher conversion rates are well documented during gaining of proficiency in laparoscopic exploration of the common bile duct.[17] Factors required to achieve a high success rate in LECBD include adequate training, standardisation of surgical technique and accurate selection of the most correct position of the mid-clavicular trochar.[18] With the continuous refinement of our operating technique, we managed to keep our conversion rate of 7% within a range reported in other series.[4,7,11,17,19] We achieved laparoscopic CBD clearance in 62 (88.7%) patients, 5 conversions and 3 subsequent endoscopic retrievals. As demonstrated in other studies, the trans-cystic approach, although considered safer, results in a significantly lower rate of CBD clearance,[10] due to anatomical variations in cystic duct insertion onto the CBD. The management of retained stones varies between institutions and depends on local expertise, availability of endoscopic facilities, patient fitness and clinical presentation of CBD stones. In our department, as we are dealing with an increasing number of patients with retained stones after failed ERCP, we have changed our policy to direct choledochotomy to improve CBD clearance. Since then, we have not used postoperative ERCP in any of our patients. However, we agree with Neoptolemos *et al.*[20] that endoscopic stone retrieval combined with endoscopic sphincterotomy has its place but should be reserved for a specific group of patients. It is particularly beneficial in acute pancreatitis, severe cholangitis (where there are residual stones), and in patients with significant co-morbidities who are not fit for surgery.

There was one peri-operative death in the primary closure group. This was a 90-year-old woman, ASA 3, with gallstone pancreatitis. Post-mortem revealed intestinal necrosis within the distribution of the superior mesenteric artery. This was presumed to be related to her pancreatitis as well as her significant cardiovascular co-morbidity. There was no evidence of a bile leak and the choledochotomy site appeared sound.

Conclusions

Primary laparoscopic exploration and closure of the CBD is at least as safe as closure with a T-tube and results in shorter operating times. Bile leaks, when treated by early re-laparoscopy, can be successfully dealt with, resulting in satisfactory patient recovery. We cannot recommend trans-cystic exploration as the method of choice due to its high incidence of retained stones that we were unable to remove

laparoscopically. We found unexpected stones in the CBD in approximately 23.9% of patients who underwent LECBD. This would represent a 4.5% rate of unexpected CBD stones during laparoscopic cholecystectomy. In our opinion, this is a strong argument in favour of a routine IOC in units where there are the skills to carry out exploratory manoeuvres. The combination of IOC and choledochoscopy ensures clearance and patency of the CBD hence routine use of a T-tube can no longer be recommended.

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